UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/685,343	10/11/00	CHARNEAU	P 03495.0197

HM12/0411
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EXAMINER	
DRABIK,C	
ART UNIT	**PAPER NUMBER**
1633	6

DATE MAILED: 04/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No. 09/685,343	Applicant(s) CHARNEAU ET AL.	
	Examiner Christopher Drabik	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Detailed Action

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1- 43, drawn to1.) a nucleic acid, comprising at least one copy of the cPPT and CTS regions of a retrovirus, **wherein said retrovirus is HIV-1**, said nucleic acid also comprising a heterologous nucleic acid sequence, wherein said heterologous nucleic acid sequence encodes a peptide, polypeptide, protein or therapeutic protein, 2.) a vector comprising said nucleic acid, wherein said vector can be an expression vector, shuttle vector, integration vector, transposon or retrotransposon, 3.) a recombinant cell comprising said vector or said nucleic acid, 4.) A process for inserting a nucleic acid of interest into the nucleus of a target cell 5.) a process for expressing a gene of interest *in vitro* and purifying the product of said gene of interest, 5.) a process for expressing a therapeutic gene of interest *in vivo* comprising the administration of a recombinant cell, 6.) a process for expressing a gene of interest *in vivo* comprising administering a nucleic acid, 7.) a process of treating an individual with a genetic disease classified 8.) a kit comprising a nucleic acid or vector comprising at least one copy of the cPPT and CTS regions of HIV-1 wherein said nucleic acid also comprises a heterologous nucleic

acid sequence classifiable in , class 424 subclass 93.21, class 435, subclasses 325 and 69.1, class 514 subclass 44, class 530 subclass 412, and class 536, subclass 24.1.

II. Claim 1- 43, drawn to1.) a nucleic acid, comprising at least one copy of the cPPT and CTS regions of a retrovirus, **wherein said retrovirus is HIV-2**, said nucleic acid also comprising a heterologous nucleic acid sequence, wherein said heterologous nucleic acid sequence encodes a peptide, polypeptide, protein or therapeutic protein, 2.) a vector comprising said nucleic acid, wherein said vector can be an expression vector, shuttle vector, integration vector, transposon or retrotransposon, 3.) a recombinant cell comprising said vector or said nucleic acid, 4.) A process for inserting a nucleic acid of interest into the nucleus of a target cell 5.) a process for expressing a gene of interest *in vitro* and purifying the product of said gene of interest, 5.) a process for expressing a therapeutic gene of interest *in vivo* comprising the administration of a recombinant cell, 6.) a process for expressing a gene of interest *in vivo* comprising administering a nucleic acid, 7.) a process of treating an individual with a genetic disease classified 8.) a kit comprising a nucleic acid or vector comprising at least one copy of the cPPT and CTS regions of HIV-1 wherein said nucleic acid also comprises a heterologous nucleic acid sequence classifiable in , class 424 subclass 93.21, class 435,

subclasses 325 and 69.1, class 514 subclass 44, class 530 subclass 412, and class 536, subclass 24.1.

III. Claim 1- 43, drawn to1.) a nucleic acid, comprising at least one copy of the cPPT and CTS regions of a retrovirus, **wherein said retrovirus is VISNA**, said nucleic acid also comprising a heterologous nucleic acid sequence, wherein said heterologous nucleic acid sequence encodes a peptide, polypeptide, protein or therapeutic protein, 2.) a vector comprising said nucleic acid, wherein said vector can be an expression vector, shuttle vector, integration vector, transposon or retrotransposon, 3.) a recombinant cell comprising said vector or said nucleic acid, 4.) A process for inserting a nucleic acid of interest into the nucleus of a target cell 5.) a process for expressing a gene of interest *in vitro* and purifying the product of said gene of interest, 5.) a process for expressing a therapeutic gene of interest *in vivo* comprising the administration of a recombinant cell, 6.) a process for expressing a gene of interest *in vivo* comprising administering a nucleic acid, 7.) a process of treating an individual with a genetic disease classified 8.) a kit comprising a nucleic acid or vector comprising at least one copy of the cPPT and CTS regions of HIV-1 wherein said nucleic acid also comprises a heterologous nucleic acid sequence classifiable in , class 424 subclass 93.21, class 435,

subclasses 325 and 69.1, class 514 subclass 44, class 530 subclass 412, and class 536, subclass 24.1.

IV. Claim 1- 43, drawn to1.) a nucleic acid, comprising at least one copy of the cPPT and CTS regions of a retrovirus, **wherein said retrovirus is EIAV**, said nucleic acid also comprising a heterologous nucleic acid sequence, wherein said heterologous nucleic acid sequence encodes a peptide, polypeptide, protein or therapeutic protein, 2.) a vector comprising said nucleic acid, wherein said vector can be an expression vector, shuttle vector, integration vector, transposon or retrotransposon, 3.) a recombinant cell comprising said vector or said nucleic acid, 4.) A process for inserting a nucleic acid of interest into the nucleus of a target cell 5.) a process for expressing a gene of interest *in vitro* and purifying the product of said gene of interest, 5.) a process for expressing a therapeutic gene of interest *in vivo* comprising the administration of a recombinant cell, 6.) a process for expressing a gene of interest *in vivo* comprising administering a nucleic acid, 7.) a process of treating an individual with a genetic disease classified 8.) a kit comprising a nucleic acid or vector comprising at least one copy of the cPPT and CTS regions of HIV-1 wherein said nucleic acid also comprises a heterologous nucleic acid sequence classifiable in , class 424 subclass 93.21, class 435,

subclasses 325 and 69.1, class 514 subclass 44, class 530 subclass 412, and class 536, subclass 24.1.

V. Claim 1- 43, drawn to1.) a nucleic acid, comprising at least one copy of the cPPT and CTS regions of a retrovirus, **wherein said retrovirus is FIV**, said nucleic acid also comprising a heterologous nucleic acid sequence, wherein said heterologous nucleic acid sequence encodes a peptide, polypeptide, protein or therapeutic protein, 2.) a vector comprising said nucleic acid, wherein said vector can be an expression vector, shuttle vector, integration vector, transposon or retrotransposon, 3.) a recombinant cell comprising said vector or said nucleic acid, 4.) A process for inserting a nucleic acid of interest into the nucleus of a target cell 5.) a process for expressing a gene of interest *in vitro* and purifying the product of said gene of interest, 5.) a process for expressing a therapeutic gene of interest *in vivo* comprising the administration of a recombinant cell, 6.) a process for expressing a gene of interest *in vivo* comprising administering a nucleic acid, 7.) a process of treating an individual with a genetic disease classified 8.) a kit comprising a nucleic acid or vector comprising at least one copy of the cPPT and CTS regions of HIV-1 wherein said nucleic acid also comprises a heterologous nucleic acid sequence classifiable in , class 424 subclass 93.21, class 435,

subclasses 325 and 69.1, class 514 subclass 44, class 530 subclass 412, and class 536, subclass 24.1.

VI. Claim 1- 43, drawn to1.) a nucleic acid, comprising at least one copy of the cPPT and CTS regions of a retrovirus, **wherein said retrovirus is CAEV**, said nucleic acid also comprising a heterologous nucleic acid sequence, wherein said heterologous nucleic acid sequence encodes a peptide, polypeptide, protein or therapeutic protein, 2.) a vector comprising said nucleic acid, wherein said vector can be an expression vector, shuttle vector, integration vector, transposon or retrotransposon, 3.) a recombinant cell comprising said vector or said nucleic acid, 4.) A process for inserting a nucleic acid of interest into the nucleus of a target cell 5.) a process for expressing a gene of interest *in vitro* and purifying the product of said gene of interest, 5.) a process for expressing a therapeutic gene of interest *in vivo* comprising the administration of a recombinant cell, 6.) a process for expressing a gene of interest *in vivo* comprising administering a nucleic acid, 7.) a process of treating an individual with a genetic disease classified 8.) a kit comprising a nucleic acid or vector comprising at least one copy of the cPPT and CTS regions of HIV-1 wherein said nucleic acid also comprises a heterologous nucleic acid sequence classifiable in , class 424 subclass 93.21, class 435,

subclasses 325 and 69.1, class 514 subclass 44, class 530 subclass 412, and class 536, subclass 24.1.

The inventions of groups I - VI are unrelated, each group distinct from the other groups. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are all drawn to distinct nucleotide sequences which have differing modes of operation based on the differing host ranges of the viruses

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claims 1-3 and 6-43 are linking claims. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims 1-3 and 6-43.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Drabik whose telephone number is 703-605-1156. The examiner can normally be reached on Monday-Friday from 9am to 5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on 703- 305-4051. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Inquiries of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234. Questions regarding review of formality issues may be directed to Kim Davis, the patent analyst assisting in this application. She may be reached at 703-305-3015.

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SUPERVISORY PATENT EXAMINER
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